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In The

Supreme Court of the United States

October Term, 1995

MEDTRONIC, INC.,

Petitioner/Cross-Respondent

v.

LORA LOHR and MICHAEL LOHR,

Respondents/Cross-Petitioners,

On Writ Of Certiorari
To The United States Court Of Appeals
For The Eleventh Circuit

BRIEF AMICUS CURIAE OF THE STATE OF CALIFORNIA IN SUPPORT OF RESPONDENTS/ CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

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QUESTION PRESENTED

Under the Medical Device Amendments to the Federal Food, Drug and Cosmetics Act, must requirements be device-specific in order to preempt state law?

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INTEREST OF AMICUS CURIAE

Pursuant to Supreme Court Rule 37.5, *Amicus Curiae*, the State of California, submits this brief in support of respondents/cross-petitioners Lora and Michael Lohr. The State of California has a strong and specific interest in preserving its traditional police power authority to enforce state statutes and regulations that protect public health and welfare. The Eleventh Circuit's decision erodes that traditional area of state regulation in a manner that leaves the citizens of the various states open to potentially devastating harm from medical devices.

One aspect of the preemption issue before this Court is of particular interest to the State. In 1986 the People of the State of California enacted the Safe Drinking Water and Toxic Enforcement Act ("Proposition 65"), California Health & Safety Code sections 25249.5 *et seq.* ("Cal. H&SC") Proposition 65 is a general "Right to Know" statute which applies to a list of several hundred chemicals that are known carcinogens and/or reproductive toxins. The statute requires that anyone, in the course of doing business, who exposes any individual to certain levels of the listed carcinogens or reproductive toxins, must first give a clear and reasonable warning to the exposed individual. Cal. H&SC § 25249.6. The warning requirement applies whether the exposure occurs from smokestack emissions, through ingestion of food, through the use of a consumer product,[1] or in any other

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[1] For consumer products containing reproductive toxins, the "safe harbor" warning language is: "**WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." 22 California Code of Regulations § 12601(b).

environment or circumstance, including through the use of a medical device.

In 1994, the federal district court for the Southern District of California ruled that Proposition 65, as it applies to dental mercury, a Class I device,[2] was preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetics Act ("MDA"). *Committee of Dental Amalgam Alloy Manufacturers and Distributors and Dentsply, Inc. v. Stratton and Lungren*, 871 F.Supp. 1278 (S.D. Cal. 1994). The court concluded that the general labeling requirements contained in 21 U.S.C. section 352(f) and 21 C.F.R. section 801.109, that apply to all medical devices or all prescription devices, were "specific requirements" that preempted Proposition 65 and prevented enforcement of that statute's warning requirement. *Dental Amalgam*, 871 F.Supp. at 1284. The State appealed and the case is pending before the Court of Appeals of the Ninth Circuit. (Nos. 94-56508 and 94-56512) While the decision in the *Dental Amalgam* appeal involves a Class I medical device, it is also possible that exposures to Proposition 65 chemicals may result

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[2] When placed in teeth dental mercury exposes the dental patient to quantities of mercury, a listed reproductive toxin under Proposition 65, thereby making it potentially subject to the warning requirements of Proposition 65.

Dental mercury was originally proposed to be classified as a Class II medical device. While recognizing that elemental mercury is a poison that posed a threat to patients with allergic reactions and to dental professionals, the FDA stated that a performance standard would not alleviate these risks and therefore classified the device as Class I. 21 C.F.R. § 872.3700; 52 Fed. Reg. 30089 (1987).

from the use of Class II and Class III medical devices. The Court's ruling therefore may equally affect the ability of the State to enforce Proposition 65 as it applies to these more dangerous devices.

One of the central questions at issue in the case before this Court – whether federal requirements under the MDA must be device specific in order to preempt state requirements – is the same as the question that is currently pending in the *Dental Amalgam* appeal.[3] Thus, the Court's ruling here may not only determine the ongoing validity of state common law tort claims as they apply to medical devices, it may equally determine the ability of the states to enforce public health and safety statutes.

Because the *Dental Amalgam* decision raises the question of preemption of statutory enactments, rather than common law claims, the State of California is filing this separate amicus brief to address that portion of the Eleventh Circuit decision that applies to statutory enactments as well as common law claims.

The State of California urges this Court to rule that only device-specific requirements under the MDA may preempt state requirements, and that the general requirements applicable to all devices or to broad categories of devices under the MDA do not preempt state law.

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[3] The State has also asserted that Proposition 65 is a requirement of general applicability not directed at medical devices and therefore is not preempted pursuant to 21 C.F.R. § 808.1(d).

SUMMARY OF ARGUMENT

This Court is faced with the intersection of federal law intended to protect consumers from harm caused by medical devices and the traditional police power of the States to regulate in the area of health and safety. While the case before the Court involves common law claims, its ruling may affect statutory enactments as well, making it more difficult or impossible for the States to perform their traditional role in safeguarding the public welfare.

In enacting the MDA, Congress established three categories of medical devices ranging from the least regulated (Class I) to the most regulated (Class III). Congress also established a two part structure of regulation. On the one hand there are the broad general controls applicable to all devices. These do not reflect any knowledge by the FDA of the particular hazards of a device or how to ensure the safety of that device. In marked contrast to the general controls are the special controls directed at specific devices and reflecting the FDA's study of the particular device and determination of how to ensure that the device is safe.

In enacting this statutory scheme, Congress specifically found that the general controls applicable to all devices were insufficient to ensure the safety and effectiveness of the Class II and III devices. 21 U.S.C. §§ 360c(a)(1)(B)(C).

The Eleventh Circuit in *Lohr v. Medtronic*, 56 F.3d 1335, 1351 (CA 11 1995) held that the general controls applicable to all devices preempt state law and prevent the States from regulating particular medical devices.

Furthermore, even though thousands of the most dangerous devices are now marketed pursuant only to the general controls and these general controls were deemed by Congress to be inadequate, under *Lohr* the states are still prohibited from exercising their traditional police powers to provide needed protection to their citizens.

Contrary to the *Lohr* decision, Congress did not intend to eradicate state law protection until the FDA exercises its own regulatory control of specific devices. It is only device-specific regulation that will assure consumers of the safety of particular medical devices and only device-specific regulation that relieves the states of their traditional duties to protect public health and welfare. Thus, contrary to the decision by the *Lohr* court, the skeletal outlines of regulation contained in the general controls do not preempt state law.

STATUTORY OVERVIEW

The State of California will not repeat the detailed description of the MDA provided to the Court by the Lohrs. A brief description, however, of the structure of regulation in the MDA is necessary to set the stage for the argument below.

The MDA's general controls, defined by 21 U.S.C. section 360c(h) as those controls authorized by sections 351, 352, 360, 360f, 360h, 360i and 360j, are applicable to all medical devices and are the skeletal outline of the regulatory scheme. The statutory general controls contain broad requirements not directed at particular devices. For example, the general controls prohibit adulterated

devices that contain filthy, putrid or decomposed substances or that do not conform to current good manufacturing practice; or prohibit misbranded devices if the labeling is false or misleading or does not contain "adequate directions for use" and warnings against use in pathological conditions. 21 U.S.C. §§ 351(a)(1), 352(a),(f).

The FDA has enacted regulatory counterparts to the statutory general controls. While these regulations are sometimes more detailed in subject matter than the statutory provisions, they are not device specific and retain the open-ended quality of the statute. For example, 21 C.F.R. section 801.109(c), one of the "Exemptions from Adequate Directions for Use," states that prescription medical devices need not comply with the "adequate directions for use" requirement of 21 U.S.C. section 352(f) if the label contains use information, and warnings, *i.e.* "hazards, contraindications, side effects, and precautions . . . . " Similarly 21 C.F.R. sections 820.1 *et seq.* simply instruct manufacturers to prepare quality assurance programs, to have sufficient personnel with appropriate training, to use buildings of suitable design and space, to use appropriately designed equipment, and the like. 21 C.F.R. §§ 820.5, 820.25, 820.40, 820.60.

In each instance, the general controls were promulgated with no knowledge of a specific device or its dangers and do not inform the manufacturer of exactly what must be done with a particular device to protect the public. Thus, the general controls initially leave to the manufacturer the decision on how to ensure the safety of a particular device. The manufacturer remains free to argue to the FDA and, if necessary, to the courts, that the general controls did not impose a particular requirement

on him or his device or that whatever actions he took were sufficient to comply with the statutory requirements.

Congress specifically found that the general controls applicable to all devices were insufficient to assure the safety and effectiveness of the more dangerous Class II and III devices[4] and therefore authorized that these devices would be subject to device specific special controls (Class II) or the premarket approval process (Class III). 21 U.S.C. § 360c(a)(1)(B),(C).

Unlike the general controls, the device specific requirements reflect careful scrutiny by the FDA of a particular device and a studied determination of how to make the device safe and effective. The contrast between the general controls, whether statutory or regulatory, and the device specific requirements is illuminated by the requirements contained in 21 C.F.R. sections 801.403 *et seq.*, a regulatory Subpart entitled "Special Requirements for ***Specific*** Devices." (emphasis added). This Subpart

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[4] Class II devices are those for which the general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device and for which the FDA can establish special controls. 21 U.S.C. § 360c(a)(1)(B).

Class III devices are those which present an unreasonable risk of illness or injury or which are used in sustaining human life or preventing impairment of human health and whose safety and effectiveness cannot be assured by the general or special controls. 21 U.S.C. § 360c(a)(1)(C).

contains, for example, device specific warning requirements,[5] testing requirements,[6] and labeling requirements.[7]

The Congressional determination that the general controls are not adequate to ensure the safety and effectiveness of the Class II and Class III devices is particularly significant because, at the time the MDA was enacted, thousands of devices were already on the market. The FDA lacked the resources to classify and regulate all of the preexisting devices[8] and to process the

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[5] Denture reliners: "*Warning* – For temporary use only. Long term use of this product may lead to faster bone loss, continuing irritation, sores and tumors. For Use Only Until A Dentist Can be Seen." (21 C.F.R. § 801.403.)

Intrauterine Devices: "Contraindications – IUDs should not be inserted when the following conditions exist: 1. Pregnancy or suspicion of pregnancy. 2. Abnormalities of the uterus resulting in distortion of the uterine cavity. . . . " 21 C.F.R. § 801.427.

[6] Impact resistant sun glasses: "In the impact test, a 5/8-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a 5/8-inch diameter. . . . " 21 C.F.R. § 801.410(d)(2).

[7] Hearing aids: "The User Instructional Brochure accompanying each hearing aid shall contain the following information. . . . : (i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment. (ii) Information on the function of all controls intended for user adjustment. (iii) A description of any accessory that may accompany the hearing aid. . . . " 21 C.F.R. § 801.420(c)(1).

[8] As the FDA noted in 1987, it lacked the resources to establish performance standards for all devices already classified or being classified as Class II devices. Therefore, "[u]nder the amendments, FDA is using the regulatory controls

premarket approval requirements for all of the preexisting Class III devices. The preexisting devices, therefore, including the most dangerous Class III devices, were "grandfathered" into the statute and were permitted to remain on the market subject only to the general controls. *See* 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Furthermore, any new devices that were substantially equivalent to the grandfathered devices were similarly allowed to enter the market through the "510(k) premarket notification process" and were subject only to the general controls applicable to all devices. *See* 21 U.S.C. § 360(k), 360c(f)(1), 360c(i)(1)(A); H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307; Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 914 (1994).

Despite the substantial passage of time since the enactment of the MDA, a large portion of all devices, including the most dangerous Class III devices, have entered the market through the premarket notification process and simply remain subject to the general controls applicable to all devices until such time as the FDA acts to classify and regulate them. H.R. Rep. No. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307. *See also* Adler and Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 914 and n. 98. These preexisting and substantially equivalent Class II and Class III medical devices therefore remain in regulatory limbo – subject to

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of class I to regulate a device classified into class II until a performance standard is established under sections 514 of the act (21 U.S.C. 360d) for a class II device." 52 Fed. Reg. 10082 (1987).

the general controls of the MDA but not yet subject to any device-specific requirements and not yet fully evaluated by the FDA for safety and effectiveness.

ARGUMENT

I. THE EXPRESS PREEMPTION PROVISION OF THE MDA SHOULD BE CONSTRUED NARROWLY TO PRESERVE THE ABILITY OF THE STATES TO PROTECT THEIR CITIZENS FROM HARM

Preemption analysis begins with the basic assumption that "the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504; 112 S.Ct. 2608, 2617; 120 L.Ed.2d 407, 422 (1992) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In determining whether an express preemption provision preempts state law, this Court in *Cipollone* held that courts must construe the express language of the statute "in light of the presumption against the pre-emption of state police power regulations." 112 S.Ct. at 2618; 120 L.Ed.2d at 424.

The presumption against preemption is particularly strong when applied to state health & safety regulations. "[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Medical Laboratories, Inc.* 471 U.S. 707, 719 (1985).

As noted above, while this Court is faced with the preemption of common law claims, its rulings may

equally affect state statutory enactments like Proposition 65, intended to warn citizens about exposures to toxic chemicals. If Congress intends to preempt statutes like Proposition 65 and to restrain the states from regulating in the traditional area of health and safety, it must do so expressly. Any expression of Congressional intent that is less than clear and manifest, and any ambiguity in the statute, must be construed against preemption.

II. ONLY DEVICE SPECIFIC REQUIREMENTS UNDER THE MDA PREEMPT STATE LAW

A. The FDA Interpretation is Consistent with the Language of the Statute

Preemption analysis begins with the express language of the statute. The preemption provision of the MDA states that:

> no State . . . may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C. § 360k(a).

While the statute does not expressly define a "requirement applicable under this chapter to the device" that is intended to be preemptive, the language at least suggests that Congress was focused on particular devices

and the requirements applicable to those particular devices.

Consistent with this language, as well as with the strong presumption against preemption of state health and safety statutes, it has been the longstanding interpretation of the FDA that preemption only applies when the FDA has enacted a device specific requirement.

> State or local requirements are preempted only when the Food and Drug Administration has established ***specific*** counterpart regulations or there are other ***specific*** requirements applicable to a ***particular*** device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the ***specific*** Food and Drug Administration requirements. 21 C.F.R. § 808.1(d) (Emphasis added).

Throughout the years, prompted in part by a concern with avoiding a "regulatory hiatus,"[9] the FDA has reiterated its view that preemption only results from device specific requirements. Thus, the Commissioner of the FDA noted that he believed that:

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[9] "Consistent with his understanding of the intent of Congress, the Commissioner has narrowly construed the preemption provisions so that section 521(a) of the act preempts State and local requirements ***only when a particular Federal requirement becomes applicable to a particular device by operation of the act***. This avoids disruption of vital State and local programs relating to the regulation of medical devices and reduces the possibility of a regulatory hiatus that could result if State or local requirements were considered preempted prior to the time FDA implemented Federal requirements." 42 Fed. Reg. 30383 (1977) (emphasis added).

> Congress intended section 521(a) [360k(a)] of the act to preempt only those different or additional State and local requirements that relate to matters already governed by ***specific, established Federal requirements applicable to a specific device***. 42 Fed. Reg. 9186 (1977) (emphasis added).

The FDA went on to note that:

> a preempting FDA requirement will become applicable to a device within the meaning of section 521(a) [360k(a)] only after FDA takes a regulatory or administrative action involving the ***application of a particular requirement of the act to a particular device***. 42 Fed. Reg. 30384 (1977) (emphasis added).

In the same discussion, the FDA provided a concrete example of the manner in which it envisioned preemption applying:

> For example, as noted in the recent regulation relating to professional and patient labeling and conditions for sale of hearing aids, State or local requirements that relate to such labeling requirements or conditions for sale ***will be preempted by section 521(a) on the effective date of the hearing aid regulation***. . . . *Id.* (emphasis added).

In other words, it is not the broad, general labeling requirements contained in 21 U.S.C. section 352(f) or 21 C.F.R. section 801.1 *et seq.* that preempt state law; it is the

device specific requirements, such as that contained in 21 C.F.R. section 801.420, that are preemptive.[10]

B. The FDA Interpretation is the Only Interpretation Consistent with the Structure and Intent of the MDA

Ultimately, the goal of preemption analysis is to determine the intent of Congress. Congress enacted the

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[10] Until relatively recently, most case law was consistent with the FDA interpretation and the courts based their preemption analysis only on device specific requirements. *See, e.g., Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-59 (CA 9 1995); *Jacobs v. DuPont*, 67 F.3d 1219, 1234-1236 (CA 6 1995); *Anguiano v. Du Pont*, 44 F.3d 806, 810 (CA 9 1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 990 (CA 8 1994); *Lamontagne v. E.I. Du Pont*, 41 F.3d 846, 853, 855 (CA 2 1994); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (CA 5 1989); *Smith v. Pingree*, 651 F.2d 1021, 1024 (CA 5 1981); *Larsen v. Pacesetter Systems, Inc.* 837 P.2d 1273, 1282 (Hawaii, 1992); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795, 812-13 (N.J., 1978).

The Eleventh Circuit in *Lohr*, is part of a series of decisions which have failed to recognize the authority of the states to protect the health and safety of their citizens and the strong presumption against preemption of that authority. *See, e.g., English v. Mentor*, 67 F.3d 477, 482 (CA 3 1995); *Duvall v. Bristol-Myers-Squibb*, 65 F.3d 392, 399 (CA 4 1995); *Feldt v. Mentor Corp.*, 61 F.3d 431, 435 (CA 5 1995); *Reeves v. Acromed*, 44 F.3d 300, 305 (CA 5), *cert.denied*, 132 L.Ed. 2d 258, 115 S.Ct. 2251 (1995); *Mendes v. Medtronic*, 18 F.3d 13, 17-18 (CA 1 1994). To the extent that these recent decisions find preemption based on the general controls applicable to all devices or to broad categories of devices, they are inconsistent with the earlier caselaw, with the recent decisions of the Second, Sixth, Eight and Ninth Circuits and with the interpretation of the FDA.

MDA in 1976 against a particular backdrop – the deaths and injuries that had occurred to many American women of child bearing age from the Dalkon Shield Intrauterine Device, a medical device largely unregulated by the Food and Drug Administration. *See* H.R. Rep. No. 853, 94th Cong. 2d Sess. 8-10 (1976) ("House Report"); Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 911-12. As a result of that and similar tragedies with other unregulated devices, Congress passed the MDA, with the expressed intent to increase consumer protection and safeguard the public health by assuring the safety and effectiveness of medical devices. House Report at 12.

The Eleventh Circuit in *Lohr v. Medtronic*, 56 F.3d 1335, 1351 (CA 11 1995) held that the general controls under the MDA preempt state requirements. Under the *Lohr* analysis, the FDA need do nothing more than issue broad, general controls applicable to all devices in order to prevent the states from exercising their traditional police powers to protect their citizens. In fact, the broader and more general the control, the greater the preemption. Even if the state has studied and examined a particular device, is aware of its dangers and knows what is needed to remedy those dangers, the state remains powerless. It can impose no device specific warning requirement and no device specific manufacturing requirement, simply because the FDA has issued a broad instruction applicable to all devices to provide necessary warnings and to use good manufacturing processes.

The anomaly set up by *Lohr* is made even more apparent when the Court considers that there are thousands of Class II and Class III devices being marketed

subject only to the general controls, controls that Congress specifically determined ***were not sufficient to ensure the safety and effectiveness of those devices***: 21 U.S.C. 360c(a)(1)(B),(C).

It is difficult to imagine that Congress established a system of general controls that it deemed to be inadequate for certain classes of devices, permitted the large majority of those devices to be marketed subject only to the general controls and then simultaneously preempted state safety and health statutes that offer consumers some additional measure of protection. If general controls are deemed to be preemptive, medical devices subject only to the general controls, including those recognized by the FDA as presenting a potential unreasonable risk of danger, would suddenly be freed from state regulation in vital areas such as warning and manufacturing processes and subject only to the same federal requirements used to regulate crutches, tongue depressors and bandages, requirements which Congress itself has recognized to be insufficient to assure the safety and effectiveness of these devices.

Given the real-world backdrop to the MDA – the deaths, miscarriages and sterility that resulted from an unregulated medical device – it is improbable that Congress intended that the general controls applicable to all devices would preempt state law and that dangerous devices would be freed from state regulation only to be ruled by the broadest and vaguest of federal requirements. Rather, the FDA interpretation of section 360k(a), that only device specific requirements can preempt state law, is a reasonable construction of the statute that comports with Congressional intent to increase consumer

protection. In order for there to be preemption of traditional state police powers to enforce health and safety statutes, the FDA must exercise its regulatory authority to study and examine a particular device and determine exactly what device-specific requirements are necessary to protect the safety of citizens relying on the device. Then, and only then, can the states relax their vigilance, knowing that the FDA has asserted full regulatory control over the device and will protect state citizens from unnecessary harm.

CONCLUSION

Thousands of dangerous medical devices remain in what might best be termed regulatory limbo, subject only to the general controls applicable to all devices, controls that Congress has determined are not adequate to assure the safety and effectiveness of these devices. Until such time as the FDA can bring to bear on these devices its full regulatory oversight and impose device-specific controls and standards, the states must be left free to fill in the interstices of the regulatory scheme and continue to protect the health and safety of their citizens. Amicus Curiae, the State of California, therefore requests that this Court rule that only device-specific requirements preempt state law and the general controls applicable to all devices or

to broad categories of devices do not preempt the police powers of the states.

Respectfully submitted,

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